

CLAIMS

We claim:

1. Polymorph Form III of N-methyl-N-(3-{3-[2-thienylcarbonyl]-pyrazol-
[1,5- α]-pyrimidin-7-yl}phenyl)acetamide.
2. The polymorph Form III of claim 1 wherein the polymorph exhibits a predominant endotherm at about 191°C as measured by as measured by a TA 2920 Modulated Differential Scanning Calorimeter (DSC) at a scan rate of 10°C per minute.
3. The polymorph Form III of claim 1 wherein the polymorph exhibits an X-ray powder diffraction pattern having characteristic peaks expressed in degrees 2θ (+/- 0.2° θ) at 18.9 and 28.1.
4. The polymorph Form III of claim 3 wherein the polymorph exhibits an additional characteristic peak expressed in degrees 2θ (+/- 0.2° θ) at 10.2.
5. The polymorph Form III of claim 4 wherein the polymorph exhibits additional characteristic peaks expressed in degrees 2θ (+/- 0.2° θ) at 13.3, 20.7, 22.2 and 30.8.
6. The polymorph Form III of claim 1 wherein the polymorph exhibits an X-ray powder diffraction pattern as shown in Figure 2.
7. The polymorph Form III of claim 1 wherein the polymorph exhibits a single crystal x-ray crystallographic analysis at 150°K with crystal parameters as the following:

Space Group	$P2_1/n$
a , Å	9.5887(3)
b , Å	10.3985(4)
c , Å	17.5807(7)
α	90

β	96.8044(14)
γ	90
Z (molecules/unit cell)	4
Calculated Density (g/cm)	1.436

8. The polymorph Form III of claim 1 wherein the polymorph exhibits a Raman FT Infrared spectrum as shown in Figure 3.

9. The polymorph Form III of claim 1 wherein the polymorph contains less than 2% by weight total impurities, less than 1% by weight water, and less than 0.5% by weight organic solvent.

10. The polymorph Form III of claim 1 wherein the polymorph contains less than 1% by weight total impurities, less than about 0.75% by weight water, and less than 0.4% by weight residual organic solvent.

11. A composition comprising polymorph Form III of N-methyl-N-(3-{3-[2-thienylcarbonyl]-pyrazol-[1,5- α]-pyrimidin-7-yl}phenyl)acetamide.

12. The composition of claim 11, further comprising N-methyl-N-(3-{3-[2-thienylcarbonyl]-pyrazol-[1,5- α]-pyrimidin-7-yl}phenyl)acetamide in a crystalline, solvate or amorphous form other than polymorph Form III.

13. The composition of claim 11 further comprising polymorph Form I.

14. The composition of claim 11 further comprising polymorph Form II.

15. A composition comprising polymorph Form III of N-methyl-N-(3-{3-[2-thienylcarbonyl]-pyrazol-[1,5- α]-pyrimidin-7-yl}phenyl)acetamide in combination with a pharmaceutically acceptable carrier.

16. The composition of claim 15 wherein the composition is formulated for oral administration.

17. The composition of claim 16 wherein the composition is in the form of a pill, capsule or tablet.

18. The composition of claim 15 wherein polymorph Form III is present in the pill, capsule or table in a unit dosage form in an amount from 0.1 to 250 mg.

19. A composition comprising (a) polymorph Form III of N-methyl-N-(3-{3-[2-thienylcarbonyl]-pyrazol-[1,5- α]-pyrimidin-7-yl}phenyl)acetamide (“Compound 1”) and (b) a crystalline, solvate, amorphous or other form of Compound 1 other than polymorph Form III, wherein the total weight of Compound 1 in the composition is the sum of (a) plus (b).

20. The composition of claim 19 wherein the composition comprises less than 0.1% by weight of polymorph Form III based on the total weight of Compound 1 in the composition.

21. The composition of claim 19 wherein the composition comprises less than 0.5% by weight of polymorph Form III based on the total weight of Compound 1 in the composition.

22. The composition of claim 19 wherein the composition comprises less than 1% by weight of polymorph Form III based on the total weight of Compound 1 in the composition.

23. The composition of claim 19 wherein the composition comprises less than 2% by weight of polymorph Form III based on the total weight of Compound 1 in the composition.

24. The composition of claim 19 wherein the composition comprises less than 5% by weight of polymorph Form III based on the total weight of Compound 1 in the composition.

25. The composition of claim 19 wherein the composition comprises less than 10% by weight of polymorph Form III based on the total weight of Compound 1 in the composition.

26. The composition of claim 19 wherein the composition comprises less than 20% by weight of polymorph Form III based on the total weight of Compound 1 in the composition.

27. The composition of claim 19 wherein the composition comprises less than 30% by weight of polymorph Form III based on the total weight of Compound 1 in the composition.

28. The composition of claim 19 wherein the composition comprises less than 40% by weight of polymorph Form III based on the total weight of Compound 1 in the composition.

29. The composition of claim 19 wherein the composition comprises less than 50% by weight of polymorph Form III based upon the total weight of Compound 1 in the composition.

30. The composition of claim 19 wherein the composition comprises at least 50% by weight of polymorph Form III based upon the total weight of Compound 1 in the composition.

31. The composition of claim 19 wherein the composition comprises at least 60% by weight of polymorph Form III based upon the total weight of Compound 1 in the composition.

32. The composition of claim 19 wherein the composition comprises at least 70% by weight of polymorph Form III based upon the total weight of Compound 1 in the composition.

33. The composition of claim 19 wherein the composition comprises at least 80% by weight of polymorph Form III based upon the total weight of Compound 1 in the composition.

34. The composition of claim 19 wherein the composition comprises at least 90% by weight of polymorph Form III based upon the total weight of Compound 1 in the composition.

35. The composition of claim 19 wherein the composition comprises at least 95% by weight of polymorph Form III based upon the total weight of Compound 1 in the composition.

36. The composition of claim 19 wherein the composition comprises at least 97% by weight of polymorph Form III based upon the total weight of Compound 1 in the composition.

37. The composition of claim 19 wherein the composition comprises at least 98% by weight of polymorph Form III based upon the total weight of Compound 1 in the composition.

38. The composition of claim 19 wherein the composition comprises at least 99% by weight of polymorph Form III based upon the total weight of Compound 1 in the composition.

39. The composition of claim 19 wherein the composition comprises at least 99.5% by weight of polymorph Form III based upon the total weight of Compound 1 in the composition.

40. The composition of claim 19 wherein the composition comprises at least 99.9% by weight of polymorph Form III based upon the total weight of Compound 1 in the composition.

41. The composition of claim 19 wherein the composition is in the form of a pill, capsule or tablet.

42. The composition of claim 19 wherein the composition is in the form of a slurry.

43. A method for treating insomnia in a patient in need thereof, comprising administering to the patient an effective amount of the composition of claim 15.

44. A method for inducing sleep in a patient in need thereof, comprising administering to the patient an effective amount of the composition of claim 15.

45. A method for inducing sedation or hypnosis in a patient in need thereof, comprising administering to the patient an effective amount of the composition of claim 15.

46. A method for inducing skeletal muscle relaxation in a patient in need thereof, comprising administering to the patient an effective amount of the composition of claim 15.